

UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA; THE	)	
STATES OF CALIFORNIA, DELAWARE	)	Civil Action No. 08-287
FLORIDA, GEORGIA, HAWAII, ILLI-	)	
NOIS, INDIANA, MASSACHUSETTS,	)	AMENDED COMPLAINT
MICHIGAN, NEVADA, NEW HAMP-	)	
SHIRE, NEW MEXICO, NEW YORK,	)	
OKLAHOMA, TENNESSEE, TEXAS,	)	
VIRGINIA, THE DISTRICT OF	)	
COLUMBIA, CONNECTICUT,	)	
LOUISIANA, MONTANA, NEW JERSEY,	)	
NORTH CAROLINA, RHODE ISLAND,	)	
WISCONSIN, and DOE STATES 1-26	)	
EX REL. [UNDER SEAL],	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
[UNDER SEAL AND UNDER SEAL],	)	
	)	
Defendants.	)	
	)	

FILED UNDER SEAL  
PURSUANT TO  
31 U.S.C. §§3729 et. seq.



Qui tam plaintiff/relator Bruce Boise, through his attorneys Phillips & Cohen, LLP and Weinstein Kitchenoff & Asher LLC, on behalf of the United States of America, the States of California, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Massachusetts, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, and Wisconsin, the District of Columbia, and any other State that enacts a False Claims Act subsequent to the filing of this Complaint (collectively “the States and the District of Columbia”), for his Complaint against defendant Cephalon, Inc. (“Cephalon”) and Takeda Pharmaceuticals North America, Inc. (“Takeda”), alleges upon personal knowledge, discussions with other persons knowledgeable about Cephalon’s and Takeda’s marketing practices, and relevant documents, as follows:

## **I. INTRODUCTION**

1. This is an action to recover damages and civil penalties on behalf of the United States of America, the States and the District of Columbia arising from false and/or fraudulent records, statements and claims made, used, and caused to be made, used or presented by Cephalon, Takeda, and/or their agents, employees and co-conspirators in violation of the Federal Civil False Claims Act, 31 U.S.C. §3729 et seq., as amended (“the FCA” or “the Act”) and its state-law counterparts: California False Claims Act, Cal. Govt Code §12650 et seq.; the Connecticut False Claims Act, Conn. Pub. Law 09-05; the Delaware False Claims and False Reporting Act, 6 Del. C. §1201 et seq.; the Florida False Claims Act, Fla. Stat. Ann. §68.081 et seq.; the Georgia False Medicaid Claims Act, Ga. Code Ann. §49-4-168 et seq.; the Hawaii False Claims Act, Haw. Rev. Stat. §661-21 et seq.; the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. §175/1-8; the Indiana False Claims and Whistleblower Protection Act, Ind. Code §5-11-5.5 et

seq.; the Louisiana Medical Assistance Program Integrity Law, La. Rev. Stat. §46:437.1 et seq.; the Massachusetts False Claims Law, Mass. Gen. Laws ch. 12 §5 et seq.; the Michigan Medicaid False Claims Act, Mich. Comp. Laws. §400.601 et seq.; the Montana False Claims Act, Mont. Code Anno. §17-8-403; the Nevada False Claims Act, Nev. Rev. Stat. Ann. §357.010 et seq.; the New Hampshire False Claims Act, N.H. Rev. Stat. Ann. §167:61 et seq.; the New Jersey False Claims Act, N.J. Stat. §2A:32C-1 et seq.; the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §27-2F-1 et seq.; the New York False Claims Act, N.Y. State Fin. §187 et seq.; the North Carolina False Claims Act, N.C. Gen. Stat. §1-605 et seq.; the Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63 §5053 et seq.; the Rhode Island False Claims Act, R.I. Gen. Laws §9-1.1-1 et seq.; the Tennessee False Claims Act (for state-or-local-government-funded claims other than Medicaid claims) and the Tennessee Medicaid False Claims Act (for state-or-state-or-local-government funded Medicaid claims), Tenn. Code Ann. §4-18-101 et seq. and §71-5-181 et seq.; the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. §36.001 et seq.; the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §8.01-216.1 et seq.; the Wisconsin False Claims for Medical Assistance Act, Wis. Stat. §20.931; and the District of Columbia Procurement Reform Amendment Act, D.C. Code Ann. §1-1188.13 et seq.

2. Damages and all other relief sought in this action relate specifically and only to Cephalon's marketing of four drugs: (a) Fentora, a successor drug to Actiq, for which Cephalon obtained FDA approval in 2006 to market for treatment of breakthrough cancer pain in adult patients who are already receiving and who are tolerant of opioid therapy for their persistent cancer pain; (b) Nuvigil, a successor drug to Provigil, for which Cephalon obtained FDA approval in June, 2007 to market for treatment for up to twelve weeks to improve wakefulness in

adult patients with excessive sleepiness associated with obstructive sleep apnea/hypopnea syndrome, narcolepsy and shift work sleep disorder; (c) Amrix, a drug that FDA approved in February, 2007 for marketing as an adjunct to rest and physical therapy to be used for up to two or three weeks for relief of muscle spasm associated with acute, painful musculoskeletal conditions in adult patients other than the elderly and for which Cephalon then purchased patent and marketing rights, and (d) Provigil, with respect to off-label promotional efforts of Cephalon's retained co-marketer, Takeda, which continued beyond the date of covered conduct under Cephalon's Provigil settlement in Relator's original suit (and until such co-promotion arrangements were terminated by Takeda in November, 2008). This behavior by Cephalon and Takeda is an outgrowth and continuation of similar misconduct by Cephalon with respect to Provigil, Gabitril and Actiq that plaintiff/relator previously alleged in a related action before this Court (settled in principal in September, 2007, and finally resolved pursuant to a settlement agreement executed in September, 2008). . Allegations in this Complaint relating to those three drugs during the period of covered conduct encompassed by that settlement are repeated herein solely for the purpose of providing background information that helps put Cephalon's more recent behavior as to Fentora, Nuvigil, Amrix, and – post September, 2007 – Provigil into historic context and helps explain why Cephalon's improper marketing behavior with respect to the drugs sued upon in this action had an immediate and wide-ranging impact.

3. Beginning not later than 2000, Cephalon embarked on a systematic practice of illegally promoting its prescription drugs. At first, such practices related to Gabitril, Provigil, and Actiq, which were at that time the only pharmaceuticals Cephalon had the right to sell for any FDA-approved indication. In addition to and in support of its off-label marketing efforts,

Cephalon's sales force offered and made unlawful financial inducements to providers to encourage them to prescribe Cephalon drugs, and/or to switch to such drugs from competitors' products. As alleged below, Cephalon disguised physician inducements as payments for "preceptorships" and speaking fees, among other things.

4. After it gained FDA approval for limited indications in June, 2006, Fentora was added to the mix of drugs Cephalon promoted off label. Similarly, soon after Cephalon gained FDA approval to market Nuvigil (June, 2007) and Amrix (February, 2007), its sales force also began marketing those drugs for off-label indications and/or in prescription quantities that exceeded approved treatment protocols. Cephalon has accelerated such marketing efforts more recently as on-label sales approached maximum potential.

5. As a direct result of Cephalon's and Takeda's improper practices, federal and state health insurance programs including, but not limited to, Medicaid, MediCal, TennCare, CHAMPUS/ TRICARE, CHAMPVA and the Federal Employee Health Benefits Program, were caused to pay false or fraudulent claims for reimbursement for off-label uses of Fentora, Nuvigil, Amrix, and Provigil which claims would not have been paid but for the defendant's illegal business practices.

6. The False Claims Act was originally enacted during the Civil War, and was substantially amended in 1986 and again in 2009. Congress amended the Act at both of these times to enhance the Government's ability to recover losses sustained as a result of fraud against the United States after finding that fraud in federal programs was pervasive and that the Act, which Congress characterized as the primary tool for combating government fraud, was in need of modernization. Congress intended that the amendments create incentives for individuals with

knowledge of fraud against the government to disclose the information without fear of reprisals or Government inaction, and to encourage the private bar to commit legal resources to prosecuting fraud on the Government's behalf.

7. The Act provides that any person who knowingly submits, or causes the submission of, a false or fraudulent claim to the U.S. Government for payment or approval is liable for a civil penalty of up to \$11,000 for each such claim, plus three times the amount of damages sustained by the Government. Liability attaches when a defendant knowingly seeks payment, or causes others to seek payment, from the Government that is unwarranted.

8. The Act allows any person having information about a false or fraudulent claim against the Government to bring an action for himself and the Government, and to share in any recovery. The Act requires that the complaint be filed under seal for a minimum of 60 days (without service on the defendant during that time) to allow the Government time to conduct its own investigation and to determine whether to join the suit.

9. Based on these provisions and similar provisions of the false claims acts of the States and the District of Columbia cited herein, qui tam plaintiff seeks through this action to recover on behalf of the United States and the States and the District of Columbia that authorize similar qui tam actions, damages and civil penalties arising from Cephalon's and Takeda's making or causing to be made false or fraudulent records, statements and/or claims in connection with its knowing off-label marketing of Fentora, Nuvigil, Amrix, and Provigil. Although neither Cephalon nor Takeda directly submitted claims for these drugs to federal and state health insurance programs, they knew and intended that their illegal off-label marketing practices and illegal inducements would cause the submission of thousands of claims to these health programs

for prescriptions that were not eligible for program reimbursement.

## **II. PARTIES**

10. Plaintiff/relator Bruce Boise is a resident of Key West, Florida. From 1996 to June, 2003, Mr. Boise was employed in Ohio by Cephalon in sales representative and sales manager positions. Concerned about Cephalon's misconduct as alleged herein, Boise voluntarily met with FDA officials in January, 2003, and has cooperated thereafter with their efforts to investigate his allegations. He was terminated by the company in 2003 because of his refusal to incorporate improper off-label marketing strategies into his sales approach and in retaliation for his having shared information regarding Cephalon's misconduct with the FDA. Since that time, Boise has been told by other persons formerly and currently affiliated with Cephalon about that company's continued off-label marketing activities.

11. Defendant Cephalon is an international biopharmaceutical company, incorporated under the laws of the state of Delaware, and headquartered at 145 Brandywine Parkway, West Chester, Pennsylvania, 19380. Its primary business activity in the United States relates to the manufacture and/or sale of the six drugs discussed in this lawsuit: Provigil, Gabitril, Actiq, Fentora, Nuvigil and Amrix. In addition, Cephalon now also owns and markets Trisonex and Treanda, two cancer treating drugs not at issue in this matter.

12. Defendant Takeda is a wholly-owned subsidiary of Takeda Pharmaceutical Company, Ltd., a Japanese corporation. Takeda is headquartered at One Takeda Parkway, Deerfield, Illinois, 60015. Its primary business activity in the United States is the marketing of drugs and other treatments for oral diabetes, insomnia, high cholesterol, and gastroenterological disorders.

### **III. JURISDICTION AND VENUE**

13. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331, 28 U.S.C. §1367 and 31 U.S.C. §3732, the last of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§3729 and 3730. Under 31 U.S.C. §3730(e), there has been no statutorily relevant public disclosure of the “allegations or transactions” in this Complaint. Relator, moreover, would qualify under that section of the False Claims Act as an “original source” of the allegations in this Complaint even had such a public disclosure occurred.

14. This Court has personal jurisdiction and venue over the defendants pursuant to 28 U.S.C. §§1391(b) and 31 U.S.C. §3732(a), which authorizes nationwide service of process, and because the defendants have minimum contacts with the United States. Moreover, defendants can be found in, reside in, and/or transact business in the Eastern District of Pennsylvania.

15. Venue is proper in this District pursuant to 31 U.S.C. §3732(a) because the defendants can be found in, and transact business in, the Eastern District of Pennsylvania. At all times relevant to this Complaint, defendants regularly conducted substantial business within the Eastern District of Pennsylvania, maintained employees and/or offices in Pennsylvania and made significant sales within Pennsylvania. In addition, statutory violations, as alleged herein, occurred in this district.

### **IV. APPLICABLE LAW**

#### **A. The FDA Regulatory Scheme**

16. Under the Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. §§ 301-97, new pharmaceutical drugs cannot be marketed in the United States unless the sponsor of the drug

demonstrates to the satisfaction of the Food and Drug Administration ("FDA") that the drug is safe and effective for each of its intended uses. 21 U.S.C. §355(a) & (d). Approval of the drug by the FDA is the final stage of a multi-year process of study and testing.

17. The FDA does not approve a drug for treatment of sickness in general. Instead, a drug is approved for treatment of a specific condition, for which the drug has been tested in patients. The specific approved use is called the "indication" for which the drug may be prescribed. The FDA will specify particular dosages determined to be safe and effective for each indication.

18. The indication and dosages approved by the FDA are set forth in the drug's labeling, the content of which is also reviewed by the FDA. 21 U.S.C. §§352, 355(d). An example of the drug's labeling is the printed insert in the drug's packaging. The FDA will only approve the new drug application if the labeling conforms to the uses and dosages that the FDA has approved. 21 U.S.C. §355(d).

19. Under the Food and Drug Administration Modernization Act of 1997 ("FDAMA"), if a manufacturer wishes to market or promote an approved drug for alternative uses - i.e., uses not listed on the approved label - the manufacturer must resubmit the drug for another series of clinical trials similar to those for the initial approval. 21 U.S.C. §360aaa (b) & (c). Until subsequent approval of the new use has been granted, the unapproved use is considered to be "off-label." "Off-label" refers to the use of an approved drug for any purpose, or in any manner, other than what is described in the drug's labeling. Off-label use includes treating a condition not indicated on the label, treating the indicated condition at a different dose, frequency, or duration than specified in the label, or treating a different patient population (e.g., treating a child